UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Lopez, et al.
Filed	:	February 9, 2004
Serial No.	:	10/774,887
For	:	Monoclonal Antibody Inhibitor of GM-CSF, IL-3, IL-5, and Other Cytokines, and Uses Thereof
Group Art Unit	:	1646
Examiner	:	Prema Maria Mertz

Commissioner for Patents
Mailstop Amendment
P.O. Box 1450
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Response to Restriction Requirement

S I R :

In response to the Office Action dated May 2, 2006, Applicants respectfully elect with traverse to prosecute the invention of Group 4, namely claims 34-35 and 38-39 which are drawn to a method of inhibiting IL-5, IL-3 or GM-CSF mediated eosinophil activitation, eosinophil production or eosinophil survival, by contacting the eosinophils *in vivo* with monoclonal antibody, classified in Class 424, subclass 141.1. Applicants respectfully request that the Examiner withdraw the restriction requirement in this application in its entirety for the reasons which are discussed below. However, as an alternative, and given the fact that the examination of Group 3 of the restriction requirement would require a search of the same class and subclass as examination of Group 4, namely Class 424, subclass 141.1, it is respectfully requested that the Examiner also consider examinaing invention Group 3 along with Group 4 in this application.

Applicants respectfully request that the Examiner withdraw the requirement for election in its entirety. The present application has a very simple claims structure, following on from the finding that antibody BION-1 is able to inhibit cytokine mediated leukemic cell proliferation, and cytokine mediated eosinophil activation, production and survival. Thus, two respective claims to methods of undertaking are presented. Although Applicants view these invention groups as being patentably distinct, they also are so closely related that examination of all claims in this

application should be pursued.

The Examining Attorney requires restriction to either the eosinophil property or the leukemic cell property. In addition, the Examining Attorney has notionally split each of the claims introducing the concept of *in vitro* and *in vivo* action.

The Examining Attorney points out that the MPEP has no provision for inventive groups that are directed to different methods, but states that restriction is deemed proper because these methods appear to constitute patentably distinct inventions. The Examining Attorney states that Inventions of grops 1 - 4 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. Therefore a search and examination of all four different methods in one patent application would result in an undue burden.

It is submitted that all claim in all patents are required to be non-coextensive otherwise there is a redundancy in claims. To that extent, all claims of any given patent application require a search for one claim to extend somewhat differently to other claims.

Notwithstanding the patentability of the individual invention groups, it is pointed out that there is a very large degree of commonality of the methods concerned, thus the same active material is used, namely a monoclonal antibody or fragments thereof capable of binding IL-5, IL-3 or GM-CSF. In groups 1 and 3, the target cells are the same namely leukemic cells and the effect on those cells are the same. In groups 2 and 4 the target cells are the same namely eosinphils, and the effect on those cells are the same. We seek the Examining Attorneys explanations of the manner in which the process steps are materially different and the manner in which the purposes are materially different such as to result in an undue burden on the Examining Attorney.

In particular with these two sets of groups it is respectfully submitted that *in vivo* and *in vitro* data is very often presented in the same document, the *in vitro* data very frequently leads onto *in vivo* data.

Should the Examining Attorney search either of these two groups combined the Examining Attorney will be search just two claims, neither of which it is submitted has particularly broad scope, whereas it is common for patent applications of this type to have very many more claims. Specific reconsideration is requested in this and it is urged that the Examiner Attorney bear these submissions in mind when assessing the burden of the search.

Applicant also points out that the claims of group 1 and group 2 (and the claims of group 3 and group 4) require searches in the *identical* class and sub class. We note that both leukemic cells and oesinophils are blood cell types, and thus both these groups are directed to a method only for ameliorating disorders of blood cells. The search for both these groups requires a search through a single subclass (as indicated by the Examining Attorney) for the activity of certain blood cells. It is submitted that this does not constitute an undue burden. The two cell types referred to have commonality in that they both have the common receptor for IL-3, IL-5 and GM-CSF.

Thus, the level of effort which would be required to examining all of the claims of the instant application is not of a level which should require restriction. It is noted that according to M.P.E.P. §803, restriction by the Examiner of patentably distinct inventions is proper if the claimed inventions are independent and a *serious burden* would be placed on the Examiner if restriction was not required. Applicants respectfully submit that the presentation of all of the pending claims would not place such a serious burden on the Examiner as to require restriction. All of the originally restricted claims of are directed to related, though patentably distinct methods, which would not impose a heavy burden of examination on the part of the Examiner.

Thus, it is Applicants' view that any search the Examiner would need to conduct in examining the instant application of all the claims would not be unduly burdensome. That would

not be to say that the examination would not be rigorous or even time-consuming, but that such effort would not meet the burden requirements of MPEP§803 in order to impose restriction. This is especially true given the fact that in order to examine all pending claims, the Examiner would be required to search two subclasses (7.24 and 141.1) in two classes (435 and 424). Thus, is respectfully submitted that the examination of all of the pending claims of Groups 1-4 of the instant application would not place such a serious burden on the Examiner as to require restriction, especially in light of the administrative efficiency gained by doing all of the claims at the same time. This is especially true, given the close relationship of the subject matter in the pending claims.

Applicants understand the general policy considerations for the Patent Office's requirement for restriction in certain instances. In this instance, however, those considerations do not weigh in favor of restricting the inventions here. In determining the appropriateness of restriction, one must also consider the countervailing consideration that, in each instance, Applicants wish the Patent Office examine their patent application with a certain degree of "administrative efficiency" and wish to have patent claims issue which reflect the breadth of their invention.

Thus, it is respectfully requested of the Examiner to withdraw the restriction requirement in its entirety. In the alternative, Applicants respectfully request the Examiner to give careful consideration to examining the inventions of both Groups 3 and 4, inasmuch as the same class and subclass would be searched in examining all the claims in those two invention groups.

No fees believed due for the presentation of this response. A petition for a three month extension of time is enclosed as is a check for the appropriate fee.

Respectfully submitted,

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Dated: August 10, 2006

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on August 10, 2006.

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